K061153

510(k) Summary for GYNESONICS Model EC6 Probe

1. SPONSOR

Gynesonics, Inc.
604 Fifth Ave. Suite D
Redwood City, CA 94063

OCT 27 2006

Contact Person:

Jessica Grossman, MD
President
Phone: (415) 317-3242
Fax: (650) 299-1566
E-mail: jgrossman@gynesonics.com

Date Prepared: January9, 2006

2. DEVICE NAME

Proprietary Name: GYNESONICS Model EC6 Probe

Common/Usual Name: Diagnostic Ultrasound Transducer

Classification Name: Diagnostic Ultrasound Transducer
(21 CFR 892.1570, 90-ITX)

3. PREDICATE DEVICES

TERASON 8EC4 Smart Probe (K03191)
TERASON 10LAP4 Smart Probe (K043278)

4. INTENDED USE

The GYNESONICS EC6 Ultrasound Transducer is intended for diagnostic ultrasound imaging or fluid flow analysis of the human body; specific indications for use are tabulated in Section 4.3 of this submission.

5. DEVICE DESCRIPTION

K061153

The GYNESONICS Model EC6 Ultrasound Transducer is intended for use with the TERATECH t3000, a portable ultrasound imaging system. Technical specifications for GYNESONICS Model EC6 the with the Model t3000 are as follows:

Probe Description (Frequency / Elements)	Array Type	Pitch (mm)	Elevation Width (mm)	Geometric Focus (mm)	Azimuth Radius (mm)	Azimuth Length (mm)
6 MHz /64	Phased	0.110	2.5	na	Flat	7.0

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The GYNESONICS Model EC6 Ultrasound Transducer is substantially equivalent to the TERASON 8EC4 and 10LAP4 Smart Probes, which are currently in commercial distribution in the United States. The GYNESONICS Model EC6 Ultrasound Transducer is similar in design and materials to the predicate probes; when operated with the TERATECH Model t3000 portable imaging system, has intended uses and a mode of operation which are a subset of those of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Gynesonics, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT 27 2006

Re: K061153
Trade Name: TERASON™ t3000 and Echo Ultrasound Systems
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: October 9, 2006
Received: October 10, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the TERASON™ t3000 and Echo Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

GYNESONICS EC6

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Ralph Shuping at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: TERASON™ t3000 and Echo Ultrasound Systems K061153

Transducer: (see comments)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Abdominal[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Intra-operative (Spec.)[d,e]	P[4]	P[4]	P[4]		P[4]	P[4]	P[4]
	Intra-operative (Neuro)	P[5]	P[5]	P[5]		P[5]	P[5]	P[5]
	Laparoscopic	P[6]	P[6]	P[6]		P[6]	P[6]	P[6]
	Pediatric[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Neonatal Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Adult Cephalic[d]:	P[1,4]	P[2,4]	P[2,4]	P[7]	P[2,4]	P[2,4]	P[2,4]
	Trans-rectal[f]:	P[2,4]	P[3,4]	P[3,4]		P[3,4]	P[3,4]	P[3,4]
	Trans-vaginal[g]:	P[2,4]	P[3,4]	P[3,4]		P[3,4]	P[3,4]	P[3,4]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Musculo-skel. (Superfic)[d]:	P[2,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[2]	P[2]	P[7]	P[2]	P[2]	P[2]
	Cardiac Pediatric	P[1]	P[2]	P[2]	P[7]	P[2]	P[2]	P[2]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1,4]	P[2,4]	P[2,4]		P[2,4]	P[2,4]	P[2,4]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal organs and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

[1] System uses previously cleared under K992505 with 3 MHz Model L3 (Linear).

[2] System uses previously cleared under K012191.

[3] System uses previously cleared under K010883.

[4] System uses previously cleared under K030191.

[5] System uses previously cleared under K040840.

[6] System uses previously cleared under K043278.

[7] System uses previously cleared under K051334.

Includes uses in military field settings in addition to hospital/clinic settings.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K061153

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: TERASON Model t3000 Portable Ultrasound System K061153
Transducer: GYNESONICS EC6
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:							
	Intra-operative (Spec.)[d,e]	N	N	N		N	N	N
	Intra-operative (Neuro)							
	Laparoscopic	N	N	N		N	N	N
	Pediatric[d]:							
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:	N[J]	N	N[J]		N[J]	N[J]	N[J]
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal organs and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
[J] Includes intrauterine scanning.
Additional Comments: P[1]: uses previously cleared under K992505 with 3 MHz Model L3 (Linear); Includes uses in military field settings in addition to hospital/clinic settings.
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation
Prescription Use (Per 21 CFR 801.109)

David A. Legan
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061153